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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,765	12/10/1999	HAROLD M. MOODY	PM265189	8046
909	7590	11/19/2003	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/457,765

Applicant(s)

MOODY ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 11, 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8, 11, 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim I, applicant is adding, "metering in the 6-APA and or ...". The specification provides support for "metering in partially the 6-APA and/or...". It would satisfy this requirement if applicant added in that limitation.

New claim 14 is not supported by the instant specification since there is no support for "a portion of the total amount of 6-APA is charged to the reaction mixture at the beginning of the reaction and the remainder is introduced during the remainder of the reaction". Since such support for this phrase cannot be found, this claim must be cancelled and thus claims 15-16 must also.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, 11, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear how "batch" defines the process. How does this distinguish the claim? The phrasing of "in the presence of an enzyme" is awkward. It would be clearer if applicant simply stated, "with a phenylglycine derivative and an enzyme to provide a reaction mixture." It is not clear where, "maintaining the total concentration in the reaction mixture" has antecedent basis. It is also unclear how one can measure the "total concentration" of 6-APA and ampicillin in the reaction mixture when the whole purpose is to produce the ampicillin. One starts with starting materials and ends up with products. It appears applicant is defining the reaction conditions by defining them in terms of the amount of starting material and ending material (product) which is confusing. In step ii), the "and or" is confusing. It would be clearer if applicant stated "and/or". In step iii), the same problem of antecedent basis of the "total quantity of phenylglycine derivative" as stated above. Further, it is confusing at what point in the reaction does the acylation occur and step ii). Applicant needs to present claim 1 with definite steps in chronological order. The metering step is a definite step not a "maintenance" step.

In claims 2 and 4, it would be clearer if applicant stated that they occurred in step i) and step ii), respectively.

Claim 8 is confusing since it is not clear how the pH controls the metering.

Claim 11 fails to further limit claim 1.

Claims 14-16 are confusing since it is not clear what a "portion" is. The term, "charged" is also confusing. What exactly is applicant trying to claim ? Further, how much is a portion ? 75 % of the total ? 2% of the total ? This claim is very confusing to the point of being meaningless.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-8, 11, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/01061 taken with WO 95/03420.

Applicant argues that the references do not show the metering step. The references are clear in that the same amount of starting materials and ending materials are used and yielded as in the claimed process. To add slowly and in a meticulous manner as in metering is well known in the art and is fully contemplated by the references. One of ordinary skill in the art reading the references would have fully realized that adding in the ingredients slowly in a meticulous fashion would work well. It is simply the choice of the artisan in an effort to optimize the results to add the ingredients in such a fashion. In fact, one would be motivated to do so since adding the ingredients in slowly gives them ample time to react properly with one another and produce a better yield of product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M V Meller', with a long horizontal stroke extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM